DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 14, 2016

GluStitch Incorporated
Mr. Tim Robinson
Regulatory and Clinical Quality Project Director
Regulatory and Clinical Research Institute Incorporated
5353 Wayzata Boulevard, Suite 505
Minneapolis, Minnesota 55416

Re: K150032
Trade/Device Name: GluStitch® Twist Tissue Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: January 8, 2015
Received: January 11, 2015

Dear Mr. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150032

Device Name
GluStitch® Twist Tissue Adhesive

Indications for Use *(Describe)*
GluStitch® Twist Tissue Adhesive is intended for the topical closure of surgical skin incisions and trauma-induced lacerations in areas of low skin tension that are simple, thoroughly-cleansed, and have easily approximated skin edges. GluStitch® Twist may be used in conjunction with, but not in place of, deep dermal stitches.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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GluStitch Inc.

www.glustitch.com Ph: (877) 940-2262 Fax: (877) 450-4000

510(K) SUMMARY

Submitted by: GluStitch, Inc.

Contact Person: Don Blacklock
President
GluStitch, Inc.
307-7188 Progress Way
Delta BC V4G 1M6
Canada
Tel: 800-667-2130
Fax: 604-940-0552
Email: blacklock@glustitch.com

Date of Summary: January 8, 2016

Device Trade Name: GluStitch® Twist Tissue Adhesive
Common or Usual Name: Topical Tissue Adhesive
Classification Name: Tissue Adhesive (21 CFR 878.4010)
Class: II
Product Code: MPN

Predicate Device(s): Indermil® Tissue Adhesive (P010002)

Device Description: GluStitch Twist Tissue Adhesive is a sterile, topical tissue adhesive containing n-butyl-2-cyanoacrylate. GluStitch Twist Tissue Adhesive is supplied in a single patient use, twist-and-use ampoule that contains at least 0.5g of liquid tissue adhesive.

Indication for Use: GluStitch Twist Tissue Adhesive is intended for the topical closure of surgical skin incisions and trauma-induced lacerations in areas of low skin tension that are simple, thoroughly-cleansed, and have easily approximated skin edges. GluStitch Twist may be used in conjunction with, but not in place of, deep dermal stitches.

Technological Characteristics (compared to predicate): The technological characteristics of the GluStitch Twist Tissue Adhesive are equivalent in performance to the predicate device Indermil Tissue Adhesive (P010002). GluStitch Twist Tissue Adhesive has been shown to be substantially equivalent and has the same performance characteristic to the predicate devices through comparison to the Indication for Use,

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formulation, technology, intended application, mechanism of action, and performance.

The GluStitch Twist Tissue Adhesive uses n-butyl-2-cyanoacrylate technology to facilitate wound closure. It is supplied sterile, in single use applicators that are designed to deliver the adhesive to the wound, to bond to the skin edges to provide wound closure and to maintain wound approximation.

The main differences between GluStitch Twist Tissue Adhesive and Indermil Tissue Adhesive relate to a minor change to the formulation to allow stability after sterilization and addition of violet D & C Violet #2 for visibility purposes.

Substantial Equivalence Rationale:

GluStitch Twist Tissue Adhesive is substantially equivalent to Indermil Tissue Adhesive (P010002) with regard to Indication For Use, formulation, technology, intended application, mechanism of action and performance at achieving its intended use.

Performance Testing:

Biocompatibility

The biocompatibility tests conducted were for a "breached or compromised surface with prolonged contact duration of greater than 24 hours but less than 30 days". All of the testing was performed using Good Laboratory Practices (GLP).

ISO 10993-5	(2009)	Biological Evaluation of Medical Devices, Part 5: Tests for *in vitro* cytotoxicity
ISO 10993-6	(2007)	Biological Evaluation of Medical Devices, Part 6: Tests for local effects after implantation
ISO 10993-10	(2010)	Biological Evaluation of Medical Devices, Part 10: Tests for irritation and skin sensitization

Sterilization and Shelf Life

Sterilization validation testing indicates a Sterility Assurance Level of 10^{-6} (SAL 10^{-6}) is obtained when GluStitch Twist Tissue Adhesive is subjected to 17.5 kGy of radiation.

Real time and accelerated aging shelf life testing has been conducted. The data from these studies support a 24 month shelf life.

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Comparative Testing

The following comparative testing demonstrated substantially equivalent performance between GluStitch Twist Tissue Adhesive and Indermil Tissue Adhesive:

- Tensile strength (ASTM F2255-05, F2258-05, F2458-05)
- Set (polymerization) time
- Heat of polymerization
- Viscosity
- Hydrolytic degradation
- Applicator expression force
- Chemical analysis

In vivo assessment of incision closure was conducted in swine, the objective of which was a 15 day GLP study to demonstrate substantial equivalence of the safety and equivalence of GluStitch Twist Tissue Adhesive to Indermil Tissue Adhesive in closing incisions. Primary safety objective evaluated the incidence of chemical burn, infection, and the histopathologic evidence of the tissue adhesive adversely affecting incision healing. Study parameters were evaluated at 4, 9 and 14 days post-closure, corresponding to Study Days 5, 10 and 15 respectively. The results demonstrate substantial equivalence of the safety and efficacy of GluStitch Twist Tissue Adhesive in relation to Indermil Tissue Adhesive for incision closure in an *in vivo* swine model.

Conclusion: Based on the non-clinical testing conducted, GluStitch Twist Tissue Adhesive is considered safe and effective when used as indicated. Performance testing has demonstrated GluStitch Twist is substantially equivalent to the legally marketed predicate device, Indermil Tissue Adhesive.